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LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

MCKENZIE, THOMAS C

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/067,094	Applicant(s) GADDAM ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 3-10, 64 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 11-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to amendments filed on 3/4/04. Applicant has amended claim 1. Claims 1, 2, and 11-63 were previously rejected. There are sixty-five claims pending and fifty-five under consideration. Claims 1, 2, and 11 are compound claims. Claims 12-23 are a composition claim. Claims 24-63 are method of using claims. This is the second action on the merits. The application concerns some α -ethoxybenzenepropanoic acid compounds, compositions, and uses thereof.

2. Examiner Truong is on leave and the case has been transferred to Examiner McKenzie. This action is non-final in view of the additional claim objection, enablement, anticipation, obviousness, and double patenting rejections newly applied.

Election/Restrictions

3. Claims 3-10, 64, and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** effective traverse in the reply filed on 3/4/04.

Response to Amendment

4. Applicants' correction of an obvious typo overcomes the objection made in point #4 of the previous office action. Applicants' deletion of "derivatives, its

analogues, its tautomeric forms" overcomes both the indefiniteness rejection made in point #5 and written description rejection made in point #6.

Claim Objections

5. Objection is newly made to claims 20-23 under 37 CFR 1.75 as being a substantial duplicate of claims 12-15. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The phrase "for the treatment of type II diabetes ..." is a statement of intent. This is a purely mental act with no physical consequences. Thus, claim 20 is a composition claim with the same limitations as claim 12.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 12-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and polymorphs of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in

scope with these claims. “The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate or polymorph, the lack of predictability in the art, and the broad scope of the claims.

c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here. There is no evidence

that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate.

Joachim Ulrich, (Kirk-Othmer Encyclopedia of Chemical Technology) writes, "Pseudopolymorphs are solvates or in the case of water as solvent, hydrates, which means crystals that incorporate solvent molecules into the crystal lattice. Pseudopolymorphs exhibit different crystal forms and/or different densities, solubilities, dissolution rates, colors, hardnesses, etc. Compared with polymorphs, there is an additional degree of freedom (than temperature and pressure), which means a different solvent or even the moisture of the air that might change the stable region of the pseudopolymorph." This means the stability of any particular solvate will depend on pressure, temperature, and humidity. Thus, solvates comprise an even less predictable art than other polymorphs.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula (I) as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed.

Cir. 1993).” That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

7. Claims 24-63 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type II diabetes, insulin resistance, and hypercholesteremia, does not reasonably provide enablement for treating the lengthy list of other claimed diseases. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with these claims. The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. The factors to be considered in making an enablement rejection have been summarized above. The four main issues are the lack of any correlation between clinical efficacy for disease treatment and Applicants' one *in vitro* assay and two *in vivo* assays, the narrow scope of working data present, the state of the prior art, and the breadth of the claims.

There is an *in vitro* assay, drawn to hPPAR_γ, described in the passage spanning paragraph 449, page 98 to paragraph 451, page 99 with data on eight compounds. There is an *in vivo* assay, drawn to glucose reduction in mice, described in the passage spanning paragraph 453, page 100 to paragraph 458, page 101 with data on a single compound. There is an *in vivo* assay, drawn to

cholesterol reduction in mice, described in the passage spanning paragraph 466, page 103 to paragraph 468, page 103 with data on seven compounds. Applicants do not state and it is not recognized in the pharmacological arts these three assays are correlated to clinical efficacy for the treatment of IBD, arteriosclerosis, and cancer, for example. There is a prophetic HMGCo enzyme assay and there are three prophetic diabetes, cholesterol lowering in the mouse, and obesity assays also described. None of Applicants compounds appear to have been tested for these therapeutic indications. The state of the clinical arts in PPAR γ related diseases is provided by Cobb (Ann. Reports Med. Chem.) that antidiabetic efficacy has been correlated to affinity to the PPAR γ binding site, in the first paragraph, page 216. Sapone (Pharmacogenetics) reports that mice lacking any PPAR α receptors develop normally. In his abstract he says that "[t]he biological significance of these novel PPARalpha alleles remains to be established".

The scope of the claims involves all of the thousands of compounds of claim 1 as well as the dozens of named diseases. Thus, the scope of claims is very broad.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue

experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Applicants cite 14 articles in support of enablement for treatment of all claimed diseases. A complete review of these references fails to reveal any use of any PPAR γ to treat all claimed disease. Applicants fail to point to any specific passages in these numerous references that support this alleged clinical correlation. Only the abstracts of each were supplied. Most are completely speculative, lacking any clinical data what so ever. None concern the entire broad scope of cancer, inflammation, or arteriosclerosis, instead discussing only narrow specific examples of disease. Ellis (Arch. Dermatol.) describes the use of troglitazone, a PPAR γ antagonists to treat psoriasis. Applicants do not claim the treatment of psoriasis. Troglitazone is structurally unrelated to the compounds of Applicants. Only the abstract of Pershadsign (Expert Opin. Invest. Drugs) was supplied. Pershadsign (Expert Opin. Invest. Drugs) states that diseases other than diabetes are discussed. What diseases and what is the evidence? Kopelovich (Cancer Ther.) appears to contain no clinical data and "may be a factor" is hardly the standard required for enablement. Kourtnikova (NY Acad. Sci.) contains no clinical data, discusses diabetes and insulin resistance, as well as the rejected diseases obesity and

hyperlipodemia. Ma (Kidney Int.) says that troglitazone, a PPAR γ antagonist, is active in an animal model of glomerulosclerosis. Applicants do not claim the treatment of glomerulosclerosis. Troglitazone is structurally unrelated to the compounds of Applicants. Nowhere does Watson (CNS Drugs) state that insulin resistance causes Alzheimer's disease. In fact in the first sentence implies that insulin resistance is a consequence of Alzheimer's disease. In any case both conditions are associated with aging, so removal of the age factor would be required before even a statistical linkage between these two conditions could be established. In any case, Applicants are not claiming treatment of Alzheimer's diseases. Messier (Beh. Brain Res.) reviews the effect of glucose, not insulin, upon memory in Alzheimer's' patients, does not state which is the cause or which is the effect, or even rule out that these are coincidental effects. Modan (Clin. Invest.) says nothing about PPAR γ antagonists and does not contain any clinical results. Further clarification of the significance of this reference is requested. Nestor (Contemp. Endocrinol.) is not even a complete abstract and says nothing about PPAR γ . Wynne (Curr. Opin. Endocrinol.) is not even a complete abstract and says nothing about PPAR γ . Legros (Rev. Argent. Endocrinol. Metab.) is not even a complete abstract and says nothing about PPAR γ . Bruning (Science)

reports on some correlations between obesity and insulin. There is nothing about PPAR γ and no clinical data.

Claim Rejections - 35 USC § 102

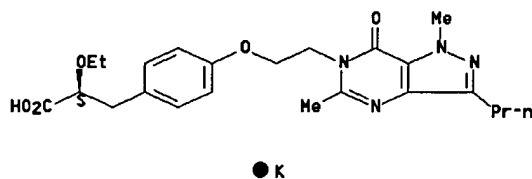
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 11-17, and 20-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Das ('816). The compound shown below fits formula (I) with M = K⁺, R¹ = ethyl, R² = R⁴ = methyl, and R³ = propyl. It has Registry Number 446291-13-0 and is found in lines 11-16, column 85 of the reference. The compound is specifically named in the present claim 11. There are approximately 140 additional anticipatory salts found in this reference. Compositions are taught in claims 21, 32, and 34 of the reference. Thus, the present claims 12, 13, 20, and 21 are taught. Compositions containing HMG CoA reductase are taught in lines 35-45, column 34. Thus, the present claims 14, 15, 22, and 23 are taught. Claim 22 of the reference teaches tablets. Thus, the present claims 16 and 17 are taught. Treatment of hyperlipemia is taught in claims 24, 37, and 45 of the reference.

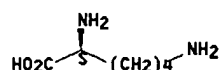
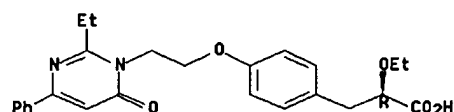
Thus, the present claims 24-29 and 48-51 are taught. The treatment of both obesity and cancer is taught in claims 24, 37, and 45 of the reference. Thus, the present claims 30-35 and 51-55 are taught. Treatment of Syndrome X is taught in claims 25, 38, and 46 of the reference. Thus, the present claims 36-41 and 56-59 are taught. Reducing serum cholesterol is taught in claims 26, 39, and 47 of the reference. Thus, the present claims 42-47 and 60-63 are taught.



The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

9. Claims 1, 2, 11-17, and 20-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Gurram ('067). The compound shown below fits formula (I) with M = L-Lysine-H⁺, R¹ = R³ = ethyl, and R⁴ = phenyl. It has Registry Number 408513-

82-6 and is found in 16-22, column 59 of the reference. The compound is specifically named in the present claim 11. There are approximately an additional 240 anticipatory salts in this reference.



Compositions are taught in claims 19, 21, 23, and 25 of the reference. Thus, the present claims 12, 13, 20, and 21 are taught. Compositions containing HMG CoA reductase are taught in the passage spanning line 57, column 37 to line 6, column 38, column 34. Thus, the present claims 14, 15, 22, and 23 are taught. Claims 20, 22, 24, and 26 of the reference teach tablets. Thus, the present claims 16 and 17 are taught. Treatment of hyperlipemia is taught in claims 28, 33, 37, 41, 45, 49, and 53 of the reference. Thus, the present claims 24-29 and 48-51 are taught. The treatment of both obesity and cancer is taught in claims 28, 33, 37, 41, 45, 49, and 53 of the reference. Thus, the present claims 30-35 and 51-55 are taught. Treatment of Syndrome X is taught in claims 29, 34, 38, 42, 46, 50, and 54 of the reference. Thus, the present claims 36-41 and 56-59 are taught. Reducing serum cholesterol is taught in claims 30, 35, 39, 43, 47, 51, and 55 of the reference.

Thus, the present claims 42-47 and 60-63 are taught.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

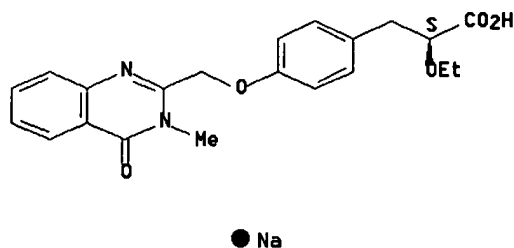
Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 12-17, and 20-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray (WO 99/8501 A2). The reference teaches the compound with registry number 220746-23-6 shown below. The Applicant claims the compounds $M = Na^+$, $R^1 = \text{ethyl}$, $R^3 = \text{hydrogen}$, $R^4 = \text{methyl}$, and an ethylene linker between the two rings. The reference teaches a compound with a methylene linker between the two rings. The compound shown in the reference in

lines 5-19, page 55. The difference between the claimed and taught compounds is the length of this linking carbon chain. It has been long established that a structural relationship varying the size of a linking carbon chain is *per se* obvious. Specifically, *In re Shetty*, 195 USPQ 753, *In re Wilder*, 195 USPQ 426 and *Ex Parte Greshem* 121 USPQ 422 all feature a compound with a C₂-link rejected over a compound with a C₁ link. Similarly, *In re Chupp*, 2 USPQ 2nd 1437 and *In re Coes*, 81 USPQ 369 have a C₁ link unpatentable over a C₂ link. *Ex parte Ruddy* 121 USPQ 427 has a C₃ link unpatentable over a C₁ link. *Ex parte Nathan*, 121 USPQ 349 found the insertion of a C₂H₄ link obvious. In all of these cases, the variation was *per-se* obvious and did not require a specific teaching. In particular, the applicant is instructed to look to *In re Shetty*, 195 USPQ 753, *In re Wilder*, 195 USPQ 426 and *Ex Parte Greshem* 121 USPQ 422 where the deletion of one carbon atom of an ethylene functionality was found to be obvious over that of the prior art.



Claim 1 of the reference is drawn to "pharmaceutically acceptable salts". Compositions are taught in claim 25 of the reference. Thus, the present claims 12,

13, 20, and 21 are made obvious. Compositions containing HMG CoA reductase are taught in claims 46 and 52 of the reference. Thus, the present claims 14, 15, 22, and 23 are made obvious. Claim 26 of the reference teaches tablets. Thus, the present claims 16 and 17 are taught. Treatment of hyperlipemia is taught in claims 27, 31, 35, and 45 of the reference. Thus, the present claims 24-29 and 48-51 are taught. The treatment of both obesity and cancer is taught in claims 27, 31, 35, and 45 of the reference. Thus, the present claims 30-35 and 51-55 are made obvious. Treatment of Syndrome X is taught in claims 29, 32, 33, 39, and 42 of the reference. Thus, the present claims 36-41 and 56-59 are made obvious. Reducing serum cholesterol is taught in claims 30, 34, 37, 40, and 46 of the reference. Thus, the present claims 42-47 and 60-63 are made obvious.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A

timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 11-17, and 20-63 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22, 24-26, 37-39, and 45-47 of U.S. Patent No. 6,444,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons cited above in point #8.

The Applicants made no remarks concerning this rejection.

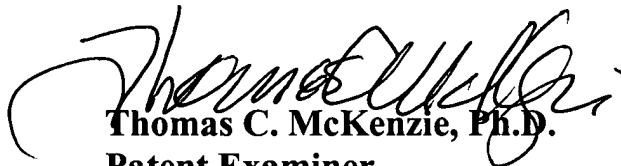
12. Claims 1, 2, 11-17, and 20-63 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 19-26, 28-30, 33-35, 37-39, 41-43, 45-47, 49-51, and 53-55 of U.S. Patent No. 6,369,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons cited above in point #9.

Conclusion

13. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

14. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK/me